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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,481	06/05/2006	Byoung-Rae Lee	3329-108	8370

6449 7590 04/06/2007

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EXAMINER	
PAK, JOHN D	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/06/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/06/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/562,481	LEE, BYOUNG-RAE	
	Examiner	Art Unit	
	JOHN PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-3 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 12/05, 6/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-3 are pending in this application.

Applicant is requested to include the application history information in the specification by adding the 371 data before the first line on page 1.

It is suggested that the parenthetical features in claim 3 be resubmitted as a dependent claim.

A minor spelling error is noted in claim 3: "pentothenate" should be spelled --- pantothenate --- . Applicant is advised to make the same correction in the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Riker et al. (US 2003/0162725).

Riker et al. explicitly disclose a caplet that contains green tea leaf extract, which contains EGCG (a polyphenol), and dicalciuim phosphate (a calcium phosphate). See paragraph 39 on page 3.

It is noted that applicant's claims require "a polyphenol extracted, isolated, and purified from green tea." However, the claims do not exclude other ingredients (see "which contains" in claim 1), so the net effect to the claim scope is that the polyphenol can be present with numerous other ingredients. Riker's EGCG-containing green tea leaf extract thus meets applicant's claim feature.

It is also noted that applicant's claims recite a composition "for lowering blood glucose." It is the Examiner's position that the EGCG in Riker's caplet would necessarily have the same effect on blood glucose level that applicant's invention would.

For these reasons, claims 1 and 3 are anticipated.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Mamana (US 2002/0192308).

Mamana explicitly discloses a tablet that contains the combination of green tea powder, green tea leaf extract that contains 50% catechin polyphenols, and calcium carbonate. See the Example formulation on page 2, paragraphs 19-29.

As discussed earlier, applicant's "a polyphenol extracted, isolated, and purified from green tea" language does not exclude other ingredients, so the net effect to the claim scope is that the polyphenol can be present with numerous other ingredients. Mamana's green tea leaf extract thus meets applicant's claim feature.

It is also noted that applicant's claims recite a composition "for lowering blood glucose." It is the Examiner's position that Mamana's tablet would necessarily have the same effect on blood glucose level that applicant's invention would, not only because it contains green tea polyphenols but also because it contains chromium (see page 1, paragraph 10).

For these reasons, claims 1 and 3 are anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Lee (WO 01/76382), Derwent abstract 1992-214190 and HCAPLUS abstract 1998:650627.

Lee discloses an extract of green tea plant, Camellia sinensis, which contains polyphenols (see page 3, line 24 & page 4, lines 22-29). Extraction, isolation and

purification steps are disclosed (page 4, lines 22-29; claims 1-2). The final form is a solid powder (see page 5, line 17; the sentence bridging pages 6-7; and claim 2). The extract has the property of decreasing the blood sugar level of diabetic patients (page 17, lines 4-9). The extract is used as a medicine for treating diabetes (claim 3). Dose of 1 g of the extract per meal is exemplified (page 11, Example 4).

Derwent abstract 1992-214190 discloses crystals of calcium carbonate to have the property of reducing the blood sugar value.

HCAPLUS abstract 1998:650627 discloses calcium carbonate obtained from egg shells to have use as antidiabetic properties. Blood sugar levels are decreased.

The difference between the claimed invention and the cited references is that the references do not explicitly disclose the combination of a polyphenol extracted, isolated, and purified from green tea and calcium. However, both components of the combination are individually known for their activity of lowering blood glucose. The motivation to combine two substances known to lower blood glucose to arrive at a third substance to lower blood glucose arises from the expectation that said third substance, the mixture, would likewise lower blood glucose and obtain the benefits of the individual substances. In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980); In re Crockett, 126 USPQ 186 (CCPA); Ex parte The NutraSweet Co., 19 USPQ2d 1586, 1587 (Bd. Pat. App. & Int. 1991).

Applicant's claim 2 requires 50-95 wt% green tea polyphenol powder + 3-30 wt% calcium. The Examiner notes here that this is merely a proportion of the two ingredients in the composition and does not actually and precisely define the amount of the polyphenol powder + calcium administered to a treated subject. As such, the proportion would have been well within the skill of the ordinary skilled artisan in this field. Both substances are known for lowering blood glucose levels, and 100% green tea polyphenol powder has been taught to be taken with food. So various percentages (dilutions) of green tea polyphenol powder is suggested from taking it with food, as long as an effective overall quantity is delivered. One having ordinary skill in the art, upon being taught of the individual blood glucose lowering properties of the two substances, would have been motivated to formulate the two substances at various proportions to deliver an effective blood glucose lowering amount of the combination to a subject in need thereof, as claimed.

Applicant's specification evidence has been given due consideration in this regard, but the evidence there is not commensurate in scope with that of the claimed subject matter. Evidence of nonobviousness, if any, must be commensurate in scope with that of the claimed subject matter. In re Kulling, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); In re Lindner, 173 USPQ 356, 358 (CCPA 1972).

Applicant's claims 1 and 3 have no limitation on the polyphenol extract amount and no limitation on the calcium amount. Claims 1-2 have no limitation on the type of

calcium compound. Applicant's specification data appears to be very limited in that only $CaCl_2$ was used and the ultimate percentage or proportion of these two substances in the administered formulation is unclear from applicant's disclosure of the experimental protocol (see discussion below).

Applicant's Table 1 on page 7 shows data with 838 mg green tea polyphenol powder + 70 mg $CaCl_2$ + 70 mg vitamin C + 2 mg iron supplement + "other excipients" (see experimental protocol on page 5, lines 18-20). The data on page 7 is therefore unclear as to (1) ultimate percentage of polyphenol powder and (2) ultimate percentage of calcium, because the weight of "other excipients" is not disclosed. This is important because if the weight of other excipients happens to be significant, applicant's data would not read on instant claim 2 since the proportional amount of polyphenol powder and calcium in the composition would then be too low.

Applicant's data in Table 2 on page 9 is unclear in that the complete formulation content of the administered formulations has not been clearly set forth. Without knowing what the content of the formulations are, evaluation of the data cannot be made. Even if assuming arguendo that the same formulations as Table 1 were used in Table 2, there would still be the problem of not knowing what the ultimate percentages of polyphenol powder and calcium were.

Applicant's data in Table 3 on page 11 is a toxicity test. Lee has already taught that the polyphenol extract is not toxic to the human body (page 5, bottom). Calcium,

the other ingredient tested by applicant for Table 3, is an essential nutritional element for the human body, so its non-toxicity would also have been plainly expected. Applicant's Table 3 shows only that which would have been expected.

For these reasons, applicant's specification data fails to show sufficient evidence of nonobviousness, which is commensurate in scope with that of the claimed subject matter.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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